

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Assessment the effect of self-foot reflexology massage on sleep quality in nurses

#### Protocol summary

##### Study aim

Determining the effect of foot reflexology massage on sleep quality in nurses

##### Design

Clinical trial with control group with parallel, randomized, on 86 nurses, four-way permutation blocking method was used for randomization.

##### Settings and conduct

The location of the project is the Intensive Care Unit (ICU), Cardiac Care Unit (CCU) and the Emergency Department of Vasei, Heshmatie and Emdad Hospitals. After obtaining written consent, nurses who are eligible to enter the study using random assignment to two groups of control (not receiving foot reflex massage) and intervention (after a training session, receiving foot reflex massage for 12 sessions) are divided. First, the demographic information form is completed by the nurses and also before the intervention and five days after the intervention, the Pittsburgh Sleep Quality Questionnaire will be completed.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Having a minimum age of 22 and a maximum of 60 years Willingness to collaborate in research Get a Pittsburgh questionnaire score greater than 5 Having healthy limbs Do not take sleeping pills No history of receiving reflective massage Exclusion Criteria: Suffering from psychological diseases Alcohol and drug addiction Having skin diseases Pregnancy and lactation

##### Intervention groups

In the intervention group, during a training session, the method of using reflective massage is taught and to ensure, they are asked to perform the intervention once in the presence of the researcher and then reflective massage two days a week for 6 weeks (12 sessions in total). ) For 30 minutes (15 minutes for each leg) 30 minutes before bedtime. During this period, follow-up is done by phone to ensure accurate intervention. The control group will not receive any intervention during the study.

##### Main outcome variables

A sleep quality score based on the Pittsburgh Sleep Quality Questionnaire

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220222054100N1**

Registration date: **2022-03-02, 1400/12/11**

Registration timing: **prospective**

Last update: **2022-03-02, 1400/12/11**

Update count: **0**

##### Registration date

2022-03-02, 1400/12/11

##### Registrant information

##### Name

Mojgan Gholitabar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 4401 8310

##### Email address

gholitabaromranim98@medsab.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-03-11, 1400/12/20

##### Expected recruitment end date

2022-05-10, 1401/02/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Assessment the effect of self-foot reflexology massage on sleep quality in nurses

**Public title**  
Assessment the effect of self-foot reflexology massage on sleep quality in nurses

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Having a minimum age of 22 and a maximum of 60 years Willingness to collaborate in research Get a Pittsburgh questionnaire score greater than 5 Having healthy limbs Do not take sleeping pills No history of receiving reflective massage  
**Exclusion criteria:**  
Suffering from psychological diseases Alcohol and drug addiction Having skin diseases Pregnancy and lactation

**Age**  
From **22 years** old to **60 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **86**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Samples will be selected by available methods and will be placed in intervention and control groups using random allocation permutation blocks. The randomization method in this study is based on quadratic blocks. These blocks consist of 2 letters (A and B). The letter A will be considered for the intervention group and the letter B for the control group. The blocks will be selected randomly and blindfolded. Each block determines the order of entry into the intervention and control groups. Thus, twenty-two quadruple blocks are formed and within each block, two people are considered as intervention people and two people as control people, and thus they will be placed in intervention and control groups. For example, assuming the ABAB block is selected from the left hand, the first and third samples will be included in the intervention group, respectively, and the second and fourth samples will be included in the control group, respectively.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Sabzevar university of medical sciences

##### Street address

No. 31, Towhid shahr Ave, Shohada Gomnam Blvd, campus of Sabzevar University of Medical Sciences, sabzevar

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

9617913112- 31 صندوق

#### Approval date

2022-02-20, 1400/12/01

#### Ethics committee reference number

IR.MEDSAB.REC.1400.163

## Health conditions studied

### 1

#### Description of health condition studied

Sleep quality of nurses

#### ICD-10 code

F51.2

#### ICD-10 code description

A lack of synchrony between the sleep-wake schedule and the desired sleep-wake schedule for the individual's environment, resulting in a complaint of either insomnia or hypersomnia

## Primary outcomes

### 1

#### Description

Percentage of people whose sleep quality score is between 5 and 21.

#### Timepoint

Measurement of sleep quality score at the beginning of the study (before the intervention) and five days after the end of the intervention

#### Method of measurement

Pittsburgh Sleep Quality Questionnaire

## Secondary outcomes

empty

## Intervention groups

## 1

### **Description**

Intervention group: Reflexology foot massage two days a week for 6 weeks (12 sessions in total) for 30 minutes (15 minutes for each leg) 30 minutes before bedtime, 5 minutes out of 15 minutes for general massage The sole of the foot and 10 minutes of massage are dedicated to the reflex points of the sole of the foot. In such a way that a constant and gentle pressure within the tolerance of each person with a slow speed and regular rhythm of 0.5 cm using the middle part of the first paragraph of the index and thumb fingers so that one third of the nail bed is white, in reflex points (point Apply to the pineal glands on the outside of the big toe, the point of the brain and the point of the solar plexus). The researcher has been taught the method of using reflective massage and the skill of performing massage and applying pressure in the desired location, and to ensure this, they are asked to perform the intervention once in the presence of the researcher.

### **Category**

Treatment - Other

## 2

### **Description**

Control group: The control group does not receive any intervention during the study and only during the study they are controlled and followed in terms of exclusion criteria and so on. Then, five days after the intervention, the Pittsburgh Sleep Quality Questionnaire will be completed by both groups and the sleep scores of the control and intervention groups will be determined.

### **Category**

N/A

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Vasei Hospital

##### **Full name of responsible person**

Mojgan Gholitabar

##### **Street address**

Vasei Hospital, Tohid Shahr Blvd, Sabzevar

##### **City**

Sabzevar

##### **Province**

Razavi Khorasan

##### **Postal code**

9617747431

##### **Phone**

+98 51 4465 1300

##### **Email**

waseehospital@medsab.ac.ir

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Heshmatie Hospital

##### **Full name of responsible person**

Mojgan Gholitabar

##### **Street address**

Heshmatie Hospital, Asadabadi Street, Sabzevar

##### **City**

Sabzevar

##### **Province**

Razavi Khorasan

##### **Postal code**

9613873136

##### **Phone**

+98 51 4401 1665

##### **Email**

heshmatie@medsab.ac.ir

### 3

#### **Recruitment center**

##### **Name of recruitment center**

Emdad Shahid Doctor Beheshti Hospital

##### **Full name of responsible person**

Mojgan Gholitabar

##### **Street address**

Emdad Shahid Doctor Beheshti Hospital, Razi Street, Sabzevar

##### **City**

Sabzevar

##### **Province**

Razavi Khorasan

##### **Postal code**

9617748189

##### **Phone**

+98 51 4464 0115

##### **Email**

Emdad@medsab.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Sabzevar University of Medical Sciences

##### **Full name of responsible person**

Fereshteh Ghorat

##### **Street address**

Vice Chancellor for Research and Technology, Towhid shahr Ave, Shohada Gomnam Blvd, campus of Sabzevar University of Medical Sciences, sabzevar

##### **City**

Sabzevar

##### **Province**

Razavi Khorasan

##### **Postal code**

9617913112

##### **Phone**

+98 51 4401 8310

##### **Email**

vcResearch@medsab.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Sabzevar University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Mojgan Gholitabar

**Position**

Master student of Internal Surgery Nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No. 31, Towhid shahr Ave, Shohada Gomnam Blvd, campus of Sabzevar University of Medical Sciences, sabzevar

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9617913112

**Phone**

+98 51 4401 8310

**Email**

mozhgan.gh15@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Mohammadreza Ghasemi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

No.31, Towhid shahr Ave, Shohada Gomnam Blvd, campus of Sabzevar University of Medical Sciences, sabzevar

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9617913112

**Phone**

+98 51 4401 8310

**Email**

ghasemimr901@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Mojgan Gholitabar

**Position**

Master student of Internal Surgery Nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

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**Postal code**

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**Phone**

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**Email**

mozhgan.gh15@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available